

Appl. No. 10/084,291
Response to Office Action of October 21, 2005
Page 11 of 15

Remarks/Arguments:

I. Introduction

Upon entry of the present amendment, claims 1-14 will remain pending in this application, although claims 12-14 have been withdrawn from consideration. Based on the following remarks, Applicants respectfully request reconsideration and allowance of the pending claims.

II. The Specification

The Examiner has objected to the specification at page 15, line 5 as not listing the complete patent number. Appropriate correction has been made.

III. Claim Objections

The Examiner has objected to claims 1, 6, and 8-11 as lacking antecedent basis or being unclear. Appropriate correction has been made.

IV. 35 U.S.C. § 103

The Examiner has rejected claims 1-11 under 35 U.S.C. § 103(a) as being unpatentable over WO 99/60939 to Brosseau in view of Bucholz et al (U.S. Patent No. 6,236,875). The Examiner states that Brosseau et al. disclose a process of performing surgery on the knee. An image is obtained, and an instrument having an attached fiducial marker is attached to the tibia and femur. The Examiner admits, however, that the Brosseau reference fails to disclose attaching a fiducial marker to an imager as well as to the instrument and the body part, but asserts that the Bucholz reference discloses a computer assisted surgical system having fiducials that are used to track the position of an imager in

Appl. No. 10/084,291
Response to Office Action of October 21, 2005
Page 12 of 15

the system in order to determine the track and position of the imager relative to the body part being imaged. The Examiner states that it would have been obvious to one skilled in the art to have modified Brosseau to include an imager with fiducials in order to properly register the images with the body part being imaged by the imager. Applicants respectfully traverse this rejection and request reconsideration and withdrawal thereof.

One of the requirements of a *prima facie* case of obviousness is that the combination of the prior art references must teach or suggest all the claim limitations. See MPEP § 2142. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art, not based on the applicant's disclosure. Moreover, the initial burden is on the Examiner to provide some suggestion of the desirability in doing what the inventor has done. In this case, one reference teaches attaching a fiducial to a body part and another reference teaches attaching a fiducial to a registration probe. Neither reference teaches both a fiducial attached to a body part *and* a fiducial attached to an imager, nor do the references teach the desirability of doing so.

First, the skeletal elements being tracked by the Bucholz reference are vertebral bodies. *See e.g.*, col. 8, lines 1-25. It would practically impossible to attach a fiducial to these anatomical points. Nor is there any teaching or suggestion to do so. In fact, to modify Bucholz as suggested would render it unsuitable for its intended purpose.¹

¹ It is well-established that if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *See In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984).

Appl. No. 10/084,291
Response to Office Action of October 21, 2005
Page 13 of 15

Second, the Bucholz reference discusses how the body parts to be tracked need to be aligned, i.e., the vertebral bodies of the spinal column are aligned in parallel. *See* col. 7, lines 30-48. The present invention, by contrast, is directed to a process for performing a high tibial osteotomy surgical operation of a portion of a tibia. It is inherent that during such a procedure, the body parts to be tracked are not aligned or parallel to one another. Accordingly, the use of the Bucholz reference to reject the claimed process does not make sense because the procedures are entirely different -- they require different steps, different instrumentation, and different needs for tracking.

Third, neither reference suggests that it would be desirable or beneficial to use multiple fiducials -- specifically, a body part fiducial, an imager fiducial, and a surgical instrument fiducial -- that are tracked by at least one position sensor. To establish *prima facie* case of obviousness for a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981 (CCPA 1974). Hindsight based on the applicant's disclosure is not permitted. In this case, the concept of a process in which a body part, an imager, and an instrument each have a fiducial attached thereto is not taught or suggested by either of the cited references, nor their combination.

Appl. No. 10/084,291
Response to Office Action of October 21, 2005
Page 14 of 15

CONCLUSION

For at least the above reasons, Applicant respectfully requests allowance of claims 1-11 and issuance of a patent containing these claims in due course. If these claims are indicated allowable, Applicants will cancel claims 12-14 without prejudice to the filing of a divisional or continuation application containing such claims. If there remain any additional issues to be addressed, the Examiner is invited to contact the undersigned attorney at 404.815.6147.

Respectfully submitted,



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